



6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL - 9670-2; Docket ID No. EPA-HQ-ORD-2007-0664]

Integrated Risk Information System (IRIS);

Announcement of 2012 Program

AGENCY: Environmental Protection Agency.

ACTION: Announcement of 2012 Program; request for information.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing the IRIS 2012 agenda and requesting scientific information on health effects that may result from exposure to the chemical substances on the agenda, including assessments that EPA is starting this year.

DATES: While EPA is not expressly soliciting comments on this notice, the Agency will accept information related to the substances included herein. Please submit any information in accordance with the instructions provided below.

ADDRESSES: Please submit relevant scientific information identified by docket ID number

EPA-HQ-ORD-2007-0664, online at www.regulations.gov (EPA's preferred method); by e-mail to ord.docket@epa.gov; by mail to Office of Environmental Information (OEI) Docket (Mail Code: 2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460-0001; or by hand delivery or courier to EPA Docket Center, EPA West, Room 3334, 1301 Constitution Avenue, N.W., Washington, DC, between 8:30 a.m. and 4:30 p.m. Monday through Friday, excluding legal holidays. The telephone number for the EPA Docket Center is 202-566-1744. Detailed instructions are provided below under **HOW TO SUBMIT INFORMATION TO THE DOCKET**.

BACKGROUND: EPA's IRIS Program is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemical substances found in the environment. Through the IRIS Program, EPA provides high quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 540 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic noncancer health effects and cancer assessments. Combining IRIS toxicity values with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances in site-specific situations and thereby support risk management decisions designed to protect public health.

EPA's process for developing IRIS assessments consists of: (1) a comprehensive search of the current scientific literature, a data call-in, and development of a draft IRIS health assessment; (2) internal EPA-wide review; (3) science consultation on the draft assessment with other Federal agencies and White House offices; (4) independent expert peer review, public review and comment, and public listening session; (5) revision of the assessment to address peer review and public comments; (6) internal EPA-wide review and interagency science discussion of EPA's disposition of peer review and public comments; and (7) clearance and posting of the final assessment on IRIS (www.epa.gov/iris).

THE IRIS AGENDA: As part of the IRIS process, EPA solicited nominations of chemicals for IRIS assessment or reassessment from EPA Program Offices and Regions, other Federal agencies and White House offices, and the public (75 FR 63827). EPA announced six general criteria for selection of chemicals for assessment or reassessment: (1) potential public health impact; (2) EPA statutory, regulatory, or program-specific implementation needs; (3) availability of new scientific information or methodology that might significantly change the current IRIS information; (4) interest to other governmental agencies or the public; (5) availability of other scientific assessment documents that could serve as a basis for development of an IRIS assessment; and (6) other factors such as widespread exposure. The decision of when to start assessments of the selected high-priority chemical substances depends on available Agency resources. Availability of risk assessment guidance, guidelines, and science policy decisions may also have an impact on the timing of EPA's decision to assess a chemical substance.

In developing the IRIS agenda for 2012, EPA conducted literature searches for the nominated chemicals and made a determination as to whether a particular chemical had sufficient information to develop at least one toxicity value. EPA offices were asked to indicate which chemicals with sufficient data were priorities for their offices. EPA then considered the other criteria as listed in the Federal Register Notice (75 FR 63827) and the capacity of the IRIS Program to begin draft development for each chemical under consideration.

EPA is soliciting public involvement in assessments on the IRIS agenda, including new assessments starting in 2012, 2013, and 2014. While EPA conducts a thorough literature search for each chemical substance, there may be unpublished studies or other primary technical sources that are not available through the open literature. EPA is soliciting scientific information from the public during the information gathering stage for the list of new assessments provided in this notice. Interested persons should provide scientific analyses, studies, and other pertinent scientific information. While EPA is primarily soliciting information on new assessments announced in this notice, the public may submit information on any chemical substance at any time.

This notice provides: (1) a list of assessments completed since the IRIS agenda was last published in October 2010 (75 FR 63827); (2) a list of IRIS assessments in progress; (3) a list of IRIS assessments that will start in 2012, 2013, and 2014; and (4) instructions to the public for

submitting scientific information to EPA pertinent to the development of assessments.

Assessments Completed

The following assessments have been completed since the last IRIS agenda was published in a Federal Register Notice on October 18, 2010 (75 FR 63827).

| CHEMICAL | CAS NO. |
|--|----------------|
| dichloromethane (methylene chloride) | 75-09-2 |
| hexachloroethane | 67-72-1 |
| 2,3,7,8-tetrachlorodibenzo- <i>p</i> -dioxin (noncancer) | 1746-01-6 |
| tetrachloroethylene (perchloroethylene) | 127-18-4 |
| tetrahydrofuran | 109-99-9 |
| trichloroacetic acid | 76-03-9 |
| trichloroethylene | 79-01-6 |
| urea | 57-13-6 |

Assessments in Progress

The following assessments are underway. The status and planned milestone dates for each assessment can be found on the IRIS Track system, accessible from the IRIS database home page (www.epa.gov/iris). IRIS assessments for all substances listed as in progress in 2012 will be provided on the IRIS website at www.epa.gov/iris as they are completed. This publicly

available website is EPA's primary location for IRIS documents. In addition, external peer review drafts of IRIS assessments are posted for public information and comment. These drafts will continue to be accessible via the IRIS and NCEA websites. Note that these drafts are intended for public information only, and do not represent the Agency's final position.

All health endpoints, cancer and noncancer, due to chronic exposure are being assessed unless otherwise noted. For all endpoints assessed, both qualitative and quantitative assessments are being developed where information is available.

| CHEMICAL | CAS NO. |
|-------------------------------------|----------------|
| acetaldehyde ¹ | 75-07-0 |
| acrylonitrile ¹ | 107-13-1 |
| ammonia ¹ | 7664-41-7 |
| arsenic, inorganic ¹ | 7440-38-2 |
| benzo(a)pyrene ¹ | 50-32-8 |
| beryllium ¹ | 7440-41-7 |
| biphenyl ¹ | 92-52-4 |
| n-butanol ¹ | 71-36-3 |
| tert-butanol | 75-65-0 |
| butyl benzyl phthalate ¹ | 85-68-7 |
| cadmium ¹ | 7440-43-9 |
| chloroethane | 75-00-3 |
| chloroform ¹ | 67-66-3 |

| | |
|--|-----------------------|
| chromium VI ¹ | 18540-29-9 |
| cobalt | 7440-48-4 |
| copper ¹ | 7440-50-8 |
| cumulative assessment for 6 phthalates | various |
| di-n-butyl phthalate ¹ | 84-74-2 |
| 1,2-dichlorobenzene ¹ | 95-50-1 |
| 1,3-dichlorobenzene ¹ | 541-73-1 |
| 1,4-dichlorobenzene ¹ | 106-46-7 |
| diethyl phthalate ¹ | 84-66-2 |
| di(2-ethylhexyl) adipate ¹ | 103-23-1 |
| di(2-ethylhexyl) phthalate ¹ | 117-81-7 |
| diisobutyl phthalate | 84-69-5 |
| diisononyl phthalate | 58033-90-2 |
| 1,4-dioxane (inhalation) ¹ | 123-91-1 |
| dipentyl phthalate | 131-18-0 |
| ethyl tertiary butyl ether (ETBE) | 637-92-3 |
| ethylbenzene ¹ | 100-41-4 |
| ethylene oxide (cancer) | 75-21-8 |
| formaldehyde ¹ | 50-00-0 |
| hexabromocyclododecane (mixed stereoisomers) | 3194-55-6, 25637-99-5 |
| hexachlorobutadiene ¹ | 87-68-3 |
| hexahydro-1,3,5-trinitro-triazine (RDX) ¹ | 121-82-4 |

| | |
|---|-----------|
| Libby amphibole asbestos | 1332-21-4 |
| methanol (cancer) | 167-56-1 |
| methanol (noncancer) ¹ | 167-56-1 |
| methyl tert-butyl ether (MTBE) ¹ | 1634-04-4 |
| naphthalene ¹ | 91-20-3 |
| nickel (soluble salts) ¹ | various |
| halogenated platinum salts and platinum compounds | various |
| polychlorinated biphenyls (PCBs) (noncancer) ¹ | various |
| polycyclic aromatic hydrocarbon (PAH) mixtures | various |
| styrene ¹ | 100-42-5 |
| 2,3,7,8-tetrachlorodibenzo- <i>p</i> -dioxin (cancer) | 1746-01-6 |
| 1,2,3-trimethylbenzene | 526-73-8 |
| 1,2,4-trimethylbenzene | 95-63-6 |
| 1,3,5-trimethylbenzene | 108-67-8 |
| uranium (natural) ¹ | 7440-61-1 |
| vanadium pentoxide ¹ | 1314-62-1 |
| vinyl acetate ¹ | 108-05-4 |

¹Reassessment of chemical currently on IRIS.

The cancer and noncancer assessments for inorganic arsenic, treated as two separate assessments in previous agendas, will be combined and proceed through the IRIS review process as one assessment. Similarly, the oral and inhalation assessments for chromium VI will be

combined and proceed through the IRIS process as one assessment. EPA will update both the noncancer and cancer beryllium assessments, rather than just the cancer assessment.

In January 2010, the IRIS assessment for methanol was released for external peer review and public comment. In June 2010, EPA decided to put the IRIS cancer assessment for methanol on hold pending a review of an underlying study by the Ramazzini Institute (RI). This review was conducted by an independent Pathology Working Group (PWG), jointly sponsored by EPA and the National Institute of Environmental Health Sciences (NIEHS), which was established to conduct a review of several RI studies including the methanol study. Based on differences of opinion between the RI and PWG scientists in diagnosing leukemias and lymphomas, EPA has decided not to rely on RI data on leukemias and lymphomas in IRIS assessments. This decision impacts the methanol cancer assessment. EPA will discontinue the peer review of the draft methanol cancer assessment and develop a new draft that does not rely on the RI study. A schedule for the development and review of the cancer assessment will be announced on IRIS track (www.epa.gov/iris). The assessment of methanol's noncancer health effects does not rely on data from the RI. Therefore, the assessment for the noncancer effects of methanol will continue through remaining steps as a separate assessment.

EPA is adding 1,2,3-trimethylbenzene (TMB) to the IRIS agenda to complete the set of three TMB isomers. Two other isomers of TMB are already included on the IRIS agenda and undergoing review (1,2,4-TMB and 1,3,5-TMB). 1,2,3-TMB is often found in the environment with 1,2,4- and 1,3,5-TMB. Given this situation, and in response to comments received in the

Agency Review and Interagency Science Consultation for 1,2,4- and 1,3,5-TMB, EPA is adding 1,2,3-TMB to the agenda and will conduct assessments of all three isomers at the same time. Because the 1,2,4- and 1,3,5-TMB assessments are already underway, EPA would appreciate notification of any additional literature as soon as possible so that this information can be included in the 1,2,3-TMB assessment prior to public comment and external peer review.

The ethanol assessment is on the IRIS agenda but has not been started. Taking into account the complexity of the ethanol dataset, EPA is considering various approaches to conducting the ethanol assessment. EPA will revisit the priority of the ethanol assessment in FY13.

New Assessments for 2012 Agenda

EPA developed a list of priority chemicals for 2012 from two sources: 1) chemicals nominated for IRIS assessment by EPA programs, other Federal agencies, and the public; and 2) chemicals already on the IRIS agenda but delayed because of resource limitations. For newly nominated chemicals, EPA first considered whether sufficient data are available to support development of one or more IRIS toxicity values. For chemicals with sufficient data, EPA considered statutory, regulatory, or programmatic need based on the stated priorities of EPA's Program and Regional Offices; potential public health impact of the assessment; interest to other levels of government or the public; and whether a partially completed draft for delayed assessments or an assessment by another organization is available that could serve as a basis for

developing an IRIS assessment.

The following chemicals have been selected for inclusion in the 2012 IRIS agenda. The projected start dates included in the table below indicate the U.S. fiscal year in which EPA will start or update literature searches for these chemicals.

EPA is requesting information from the public for consideration in the development of these assessments. Instructions on how to submit information are provided below under **HOW TO SUBMIT INFORMATION TO THE DOCKET**.

| CHEMICAL | CAS NO. | PROJECTED START |
|---|----------------|------------------------|
| antimony ^{1,3} | 7440-36-0 | FY13 |
| carbonyl sulfide ^{1,3} | 463-58-1 | FY12 |
| chlorobenzene ^{2,3} | 108-90-7 | FY13 |
| decamethylcyclopentasiloxane (D5) ² | 541-02-6 | FY13 |
| octamethylcyclotetrasiloxane (D4) ² | 556-67-2 | FY13 |
| 1,2-dichloroethane (ethylene dichloride) ^{1,3} | 107-06-2 | FY14 |
| diisopropyl ether (DIPE) ¹ | 108-20-3 | FY12 |
| tert-amyl methyl ether (TAME) ¹ | 994-05-8 | FY12 |
| 4,4'-dimethyl-3-oxahexane (TAEE) ¹ | 919-94-8 | FY12 |
| isopropanol ¹ | 67-63-0 | FY13 |
| manganese ^{1,3} | 7439-9 | FY13 |

| | | |
|--|--------------------|------|
| mercury, elemental ^{2,3} | 7439-96-5 | FY14 |
| methyl mercury ^{2,3} | 22967-92-6 | FY14 |
| tungsten and related compounds ¹ | 7440-33-7, various | FY14 |
| vanadium, elemental and compounds ² | various | FY13 |

¹ Chemical was previously on the IRIS agenda but assessment was delayed due to resource limitations.

² Chemical is a new addition to IRIS agenda.

³ Reassessment of chemical currently on IRIS.

By FY14, EPA will have started all of the chemicals that were previously on the IRIS agenda, but delayed because of resource limitations, except for the chemicals that are being withdrawn from the agenda as described below under **Withdrawn Assessments** and the ethanol assessment, described above under **Assessments in Progress**. Among the new additions to the IRIS agenda, chlorobenzene, mercury, methyl mercury, and vanadium were selected for assessment because they are priorities for multiple EPA Program Offices and Regions and all chemicals have the potential for high impact on public health. While only two EPA Offices indicated that the siloxanes are priorities, D4 and D5 were selected for IRIS assessment because they met other criteria including high potential for impact on public health and widespread exposure and because of the opportunity afforded to perform a cumulative assessment of emerging contaminants.

One of the highest priority substances nominated for assessment was lead. EPA will defer a decision on the development of an IRIS assessment for lead until the end of 2012. EPA anticipates publication of a final Integrated Science Assessment (ISA) for lead during the

summer of 2012. The ISA offers a comprehensive summary of the health and ecological scientific evidence and also includes information on lead sources, ambient air concentrations, fate and transport, exposure, and toxicokinetics. A draft ISA is available at <http://epa.gov/ncea/isa/lead.htm>. In addition, the National Toxicology Program (NTP) anticipates completion in 2012 of a draft *Monograph on Health Effects of Low-Level Lead*, which summarizes the health evidence in humans related to major effects with a focus on blood lead levels <10 ug/dL. A draft NTP report, available at <http://ntp.niehs.nih.gov/go/36639>, has been reviewed by an NTP Peer Review Panel. Upon completion, these documents will be evaluated to determine if an IRIS assessment is needed.

In FY2013, before beginning draft development, EPA will conduct a state-of-the-science workshop on manganese. Similarly, in FY2014, EPA will conduct a state-of-the-science workshop on elemental mercury and methyl mercury. These meetings will be open to the public.

Withdrawn assessments

The following chemicals are withdrawn from the IRIS agenda:

| CHEMICAL | CAS NO. |
|---------------------------|----------------|
| alkylates | various |
| bisphenol A | 80-05-7 |
| mirex | 2385-85-5 |
| refractory ceramic fibers | not applicable |

The alkylates are a distillation fraction of petroleum and are present in gasoline. Common alkylates found in gasoline for which IRIS assessments have not been recently completed include n-heptane, methylcyclohexane, 2-methylbutane, 2-methylpentane, 3-methylpentane, n-octane, 2,3,3-trimethylpentane, 2,3,4-trimethylpentane, and 2,2,5-trimethylhexane. This class of chemicals is withdrawn from the IRIS agenda because there are multiple chemicals in the class, many with limited databases. If individual alkylates with sufficient data to support an IRIS assessment are nominated in the future, the IRIS Program will consider these nominations individually. Bisphenol A is withdrawn because EPA is awaiting further analysis and results from the U.S. Food and Drug Administration and the NIEHS prior to determining whether Agency action under the Toxic Substances Control Act is required for protection of human health. Refractory ceramic fibers and mirex are withdrawn because they are no longer priorities for EPA.

We continue to request the submission of any scientific information that you would like EPA to consider for any assessment on the IRIS agenda. Instructions for submitting information are provided below.

HOW TO SUBMIT INFORMATION TO THE DOCKET: Submit your information, identified by Docket ID No. EPA-HQ-ORD-2007-0664, by one of the following methods:

- <http://www.regulations.gov>: Follow the online instructions for submitting comments.
- E-mail: ORD.Docket@epa.gov.

- Facsimile: 202-566-1753.
- Mail: Office of Environmental Information (OEI) Docket (Mail Code: 2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. The telephone number is 202-566-1752. If you provide comments by mail, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.
- Hand Delivery: The OEI Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Avenue, N.W., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202-566-1744. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by hand delivery, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at <http://www.regulations.gov>, including any

personal information provided, unless comments include information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> website is an “anonymous access” system, which means that EPA will not know your identity or contact information unless you provide it in the body of your comments. If you send e-mail comments directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comments that are placed in the public docket and made available on the Internet. If you submit electronic comments, EPA recommends that you include your name and other contact information in the body of your comments and with any disk or CD-ROM you submit. If EPA cannot read your comments due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comments. Electronic files should avoid the use of special characters and any form of encryption and be free of any defects or viruses. For additional information about EPA’s public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at <http://www.regulations.gov> or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

ADDITIONAL INFORMATION: For information on the docket or www.regulations.gov, please contact the Office of Environmental Information (OEI) Docket (Mail Code: 2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460; telephone: 202-566-1752; facsimile: 202-566-1753; or e-mail: ORD.Docket@epa.gov.

For information on the IRIS program, contact Karen Hammerstrom, IRIS Program Deputy Director, National Center for Environmental Assessment, (Mail Code: 8601P), Office of Research and Development, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460; telephone: 703-347-8642; or e-mail: [FRN Questions@epa.gov](mailto:FRN_Questions@epa.gov).

For general questions about access to IRIS, or the content of IRIS, please call the IRIS Hotline at 202-566-1676 or send electronic mail inquiries to hotline.iris@epa.gov.

Dated: April 30, 2012.

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